IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff, v. Undetermined quantities of various articles of food, dietary supplements, including finished products, in-process granules, and re-work granules, in various sizes and types of containers, unlabeled, labeled, or otherwise identified as follows: SynVita SynCell SynPhyto-K DigestiveCare JointCare SynOmega and Undetermined quantities of various articles of food and drug, including finished products, in-process granules, and re-work granules, in various sizes and types of containers, unlabeled, labeled, or otherwise identified as follows: SynBio SynOPC BoneCare SynBio-X SynOPC-X VisionCare CardioCare SynGevity Defendants.	)	Civil No. 11-cv-771 **FILED UNDER SEAL**

VERIFIED COMPLAINT FOR FORFEITURE IN REM

The United States of America ("United States"), by its attorney Carol L. Wallack, Trial Attorney, Consumer Protection Branch, United States Department of Justice, hereby states and alleges as follows:

NATURE OF THE ACTION

1. This Complaint is filed by the United States, and requests seizure and condemnation of the articles of food and drug, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. §§ 301 *et seq*.

2. There are at Hillsboro, Wisconsin, in the possession of Syntec Inc., d/b/a Syntec Nutraceuticals ("Syntec Nutraceuticals"), 186 East Madison Street, or elsewhere within the jurisdiction of this Court, articles of food and drug, as described in the caption, which articles consist in whole or in part of components that were shipped in interstate commerce from outside the State of Wisconsin (the "Articles").

JURISDICTION AND VENUE

3. Plaintiff brings this action *in rem* in its own right to condemn and forfeit the Articles. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides the Court with jurisdiction over seizures brought under the Act.

4. This Court has *in rem* jurisdiction over the articles because they are located in the Western District of Wisconsin. Upon the filing of this Complaint, the United States requests that

this Court issue an arrest warrant *in rem* pursuant to Federal Rules of Civil Procedure Supplemental Rule G(3)(b), which the United States will execute upon the articles pursuant to Supplemental Rule G(3).

BASIS FOR FORFEITURE

5. The articles of food (dietary supplements) are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet the current good manufacturing practice (CGMP) requirements for dietary supplements. *See* 21 C.F.R. Part 111.

6. Certain of the Articles (SynBio, SynOPC, SynBio-X, SynOPC-X, VisionCare, CardioCare and SynGevity) are also drugs within the meaning of 21 U.S.C. § 321(g)(1) because they are promoted for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Such Articles may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 355(a), because they are "new drugs" within the meaning of 21 U.S.C. § 321(p) and no approvals of applications filed pursuant to 21 U.S.C. §§ 355(b) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) are in effect for such drugs.

7. The articles of drug are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 C.F.R. § 201.115 because the articles are unapproved new drugs.

8. By reason of the foregoing, the Articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

FACTS

9. Syntec Nutraceuticals is a manufacturer and distributor of various products that it labels and promotes as dietary supplements. All products are sold using direct marketing through individuals ("distributors") who buy and resell the products to their customers. The firm provides these distributors with a distributor kit containing materials to start their businesses. Additional marketing materials, including CDs and DVDs, are available for distributors to purchase at www.syntecshop.com.

10. In a Warning Letter issued on March 13, 2009, the Food and Drug Administration ("FDA") advised Syntec Nutraceuticals that claims on the firm's website, www.syntecworld.com, cause their products to be drugs under 21 U.S.C. § 321(g) and new drugs that may not be marketed in interstate commerce pursuant to 21 U.S.C. §§ 321(p) and 355(a), and that the drug products were misbranded pursuant to 21 U.S.C. § 352(f)(1). In a response dated March 27, 2009, Syntec Nutraceuticals stated that it had completed a full review of its website and implemented changes as recommended, including revision of all product descriptions and removal of select video testimonials and references to medical studies. In addition, Syntec Nutraceuticals stated it had discontinued printing and distributing promotional literature that was not compliant. The company promised that future editions would contain "compliant copy" as seen on the updated website.

11. During a subsequent FDA inspection, conducted from October 13 through November 3, 2010, an FDA investigator found that Syntec Nutraceuticals continued to include

disease claims for its products in video testimonials on the firm's website and in videos available via a link on the firm's website to www.youtube.com/user/SyntecInc; in product testimonials in promotional literature; on the firm's Health Seminar DVD #1 and #2; and through articles referenced on the Syntec website, including at least one article previously cited in the March 13, 2009 Warning Letter.

12. Another FDA inspection conducted between June 6 and 17, 2011 found that the firm continued to make disease claims, causing its SynOPC and SynOPC-X, VisionCare, BoneCare, CardioCare, SynBio and SynBio-X, and SynGevity products to be drugs within the meaning of 21 U.S.C. § 321(g). Such claims were made in interviews found on the firm's website and via a link on the firm's website to www.youtube.com/user/SyntecInc, and in product descriptions in the firm's Health &Wealth CD, available for distributors and customers to purchase at www.syntecshop.com.

13. Examples of the claims that cause the products to be drugs include, among others:

(a) SynOPC and SynOPC-X:

(i) "OPCs can help alleviate asthma and allergic rhinitis, and decrease risk of cardiovascular disease;" and

(ii) "My health was really deteriorating. The worst thing was my allergies. I've had allergies since I was a teenager. . . . So every change of season, I'd be sick. Very, very bad allergies, I need[ed] to take allergy shots. Sometimes I'd be in bed for two or three weeks and my son would have to take me to see the doctor. . . . After using . . . OPC . . . my allerg[ies] chang[ed]. . . . The most encouraging for me was [the change in] the allergy symptoms . . . ;"

(b) VisionCare: "VisionCare can help decrease the risk of developing cataracts,

glaucoma, and age-related macular degeneration, the three most common causes of vision loss in adults;"

(c) BoneCare: "Inulin [an ingredient of BoneCare] also . . . helps to reduce LDL cholesterol . . . ;"

(d) CardioCare: "Can help lower LDL cholesterol, [and] total cholesterol . . . . Can help reduce the risk of blood clot formation;"

(e) SynBio and SynBio-X: "I received an e-mail [from an individual] . . . and she sent this: . . . 'Just wanted to let you know that I've been taking SynBio-X every evening since I saw you last and I was so impressed with the results . . . . I've been struggling with Candida,' which is a yeast infection, a fungal infection . . . [that is] very difficult to get rid of . . . . She's been working on it for the last 11 months trying prescription drugs, probiotics from other companies . . . . She sa[id] . . . 'it only took three days for all the symptoms to subside';"

(f) SynGevity: "Resveratrol [an ingredient of SynGevity] has caught the attention of prominent scientists everywhere, including Ph.D.s at Harvard Medical School. [A doctor at] Harvard Medical School recently published his discovery that resveratrol allowed mice to live 30% longer . . . [and] also protected them from diabetes."

14. Subsequently, an inspection conducted on September 19 and 20, 2011 confirmed that the video interviews and Health &Wealth CD containing the above disease claims remained available.

15. During the September 19 and 20, 2011 inspection, FDA investigators also observed significant violations of the CGMP requirements for dietary supplements. Syntec's violations of the CGMP requirements include, but are not limited to:

(a) Failure to document that the finished dietary supplement meets established specifications, as required by 21 C.F.R. §§ 111.70(e) and 260(i).

(b) Failure of the master manufacturing record to include the identity specifications for the points, steps, or stages in the manufacturing process where control is necessary, as required by 21 C.F.R. § 111.205(b)(1), and failure to establish controls and procedures that ensure that each batch of dietary supplement meets the specifications identified, as required by 21 C.F.R. § 111.205(b)(2).

(c) Failure of the master manufacturing record to include procedures for sampling and a cross-reference to procedures for tests or examinations, and to include corrective action plans for use when a specification is not met, as required by 21 C.F.R. §§ 111.210(h)(2) and (h)(5).

(d) Failure of the batch production record to include complete information relating to the production and control of each batch, as required by 21 C.F.R. § 111.255(b).

(e) Failure of the batch production record to include the results of any testing or examination performed during the batch production or a cross-reference to such results, or to include documentation that the finished dietary supplement meets specifications established in accordance with 21 C.F.R. § 111.70(e) and (g), as required by 21 C.F.R. § 111.260(h) and (i).

16. FDA investigators observed similar failures to meet the CGMP requirements for dietary supplements during the October 13 through November 3, 2010 inspection and the June 6 through 19, 2011 inspection.

WHEREFORE, the United States requests that a warrant of arrest for the Articles, as identified in the caption, be issued; that due notice be given to all parties to appear and show cause why the seizure and condemnation should not be decreed; that the judgment be entered

declaring the articles of food and drug be condemned and disposed of according to law; and that the United States be granted such other and further relief as this Court may deem just and proper, together with cost and disbursement of this action.

Dated this the 15th day of November, 2011.

Respectfully submitted,

s/

CAROL L. WALLACK
Trial Attorney
Consumer Protection Branch
United States Department of Justice
450 Fifth Street, N.W., Room 6246
Washington, DC 20001
Tel: (202) 307-0486
Carol.Wallack@usdoj.gov

OF COUNSEL:
Scott A. Kaplan
Trial Attorney
Food and Drug Division
Office of General Counsel
U.S. Dep't of Health & Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

DECLARATION

I am a Compliance Officer for the Food and Drug Administration, United States Department of Health and Human Services, and am familiar with the investigation of this case, and the evidence gathered in support thereof. I have personally reviewed the internet websites in question, the labeling obtained by FDA, and the FDA's official records related to this case.

I have read the contents of the foregoing Complaint for Forfeiture and based on my personal knowledge of the evidence obtained in the course of my official duties and as a result of my review of FDA's official business records, the statements contained therein are true to the best of my knowledge and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 15th day of November, 2011.

Melissa I. Michurski
Compliance Officer
Food and Drug Administration
Department of Health and Human Services